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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,971	04/13/2000	Sarah Liljegren	19452A-000700US	7002

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EXAMINER
KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

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24

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Ble Copy

Office Action Summary	Application No.	Applicant(s)	
	09/548,971	LILJEGREN ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,9-18,20-28,30 and 34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,9-18,20-28,30 and 34-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *14* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of the Application

1. This Office action is in response to Applicant's Amendment and Remarks filed 15 October 2002.

2. Claims 1-4, 8, 19, 29 and 31-33 have been cancelled and new claims 34-40 have been added as requested in the response filed 15 October 2002.

3. The Draftsman has approved the formal drawing filed 15 October 2002.

4. The Botterman Declaration and the Yanofsky Declaration, both filed on 15 October 2002, under 37 CFR § 1.132 have been considered and will be addressed below.

5. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims or Applicant's arguments.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

7. Claim 5 is objected to because of the following informalities: lines 7 and 8 appear to be a method step within a product claim and thus the claim is confusing as to whether a product or a method is being claims. Replacing the word "and" at line 6 with -- wherein --, as in claim 34 would obviate this rejection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 5 and 9-18 remain rejected and claims 34-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 May 2002. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant argues that the specification defines a physical and structural property of the invention and that the claims only encompass polynucleotides encoding polypeptides with a particular function, the ability to delay fruit dehiscence when introduced to suppress IND1 expression (page 7 of the Remarks). This argument is not found to be persuasive because other than function, Applicant has only described the encoded polypeptides by the physical property as being a bHLH domain transcription factor. It is art recognized that the specific function of plant transcription factors cannot be described based only on the structural feature that they are of a particular family of transcription factor; structure does not equate to specific function in relation to plant transcription factors.

Applicant argues that the Yanofsky Declaration demonstrates that two additional gene products from *Brassica napus* are at least 70% identical to SEQ ID NO: 2 and have the same function as the *Arabidopsis IND1* gene product (page 7, 4th paragraph of the remarks). This argument is not found to be persuasive because the arguments related to the Yanofsky Declaration do not obviate the lack of written description by Applicant at the time of the invention. Knowledge, after the fact, cannot be used to overcome a lack of written description in the instant case.

At new claims 34-40, fails to adequately describe a polynucleotide comprising at least 200 contiguous nucleotides of SEQ ID NO: 1, or said polynucleotide being 65% identical to at least 200 contiguous nucleotides of SEQ ID NO: 1, or an expression cassette comprising said polynucleotide. See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself". Applicant only describes a polynucleotide that encodes a polypeptide having the sequence of SEQ ID NO: 2, exemplified in SEQ ID NO: 1. The instant claims are directed to introduction of polynucleotide fragments that suppress IND1 expression resulting in a plant with delayed fruit dehiscence. Applicant has failed to adequately describe fragments of a polynucleotide having the sequence of SEQ ID NO: 1 that could be used in the claimed expression cassette, and only presents a statement for any such polynucleotide being at least 65% identical to said fragments. Hence, it remains unclear from the instant specification that Applicant was in possession of the inventions as broadly claimed.

9. Claim 12 remains rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 May 2002. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant argues that the claim does not require activity in a heterologous plant (page 8, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the Examiner stated that "Applicant does not teach that positions from about 1-2764 or 3362-3856 of SEQ ID NO: 1 encode promoter/regulatory elements.". The art to which the Examiner referred in the previous Office action demonstrated that one of skill in the art cannot reasonable predict that a polynucleotide will function as a dehiscence zone specific promoter without an actual reduction to practice because one of skill in the art cannot reasonably predict what portions of a polynucleotide functions as a promoter and what portions function to specifically regulate promoter activity.

10. Claims 20-28 and 30 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of delaying fruit dehiscence in *Arabidopsis thaliana*, does not reasonably provide enablement for a method of delaying fruit dehiscence in any plant using the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 May 2002. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

Applicant argues that the cited art only discussed the effect of positive expression and not co-suppression of heterologous sequences in an attempt to complement mutations and that said art does not comment in any way about the effect of suppression of expression (paragraph spanning pages 8-9 of the Remarks). This

argument is not found to be persuasive because the teachings of Quattrocchio were cited to illustrate that polynucleotides encoding heterologous bHLH transcription factors do not predictably function in a similar manner as said bHLH transcription factors function in the homologous plant. Hence, it is reasonable to infer that co-suppression with a heterologous polynucleotide encoding a heterologous bHLH transcription factor will not predictably function either. The instant claims are not limited to delaying fruit dehiscence in an *Arabidopsis* plant, but to any plant, whose fruit dehisces.

Applicant argues that screening does not amount to undue experimentation (paragraph spanning pages 9-10 of the Remarks). The Examiner cited Colliver *et al* who teaches that expressing of a heterologous antisense construct is unpredictable and can lead to unpredicted molecular and biochemical phenotypes. The Examiner maintains that given the limited guidance by Applicant for a method using antisense constructs and identifying tissue and regulatory specific promoter regions it would have required undue trial and error experimentation by one of ordinary skill in the art at the time of Applicant's invention to practice the invention as broadly claimed. The use of antisense constructs was not routine in the art at the time of Applicant's invention, and had been mainly used to suppress expression of a protein in the homologous plant, from which the coding sequence had been isolated.

11. Claims 34-40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are directed to an expression cassette comprising a polynucleotide at least 65% identical to at least 200 contiguous nucleotides of SEQ ID NO: 1, wherein introduction of the expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence. But the instant specification does not teach one of skill in the art how to make and use such an expression cassette comprising a polynucleotide to delay fruit dehiscence in a transformed plant. Applicant has only taught how to make and use a polynucleotide having the sequence of SEQ ID NO: 1 in an expression cassette to co-suppress expression of the IND1 gene in *Arabidopsis* (pages 36-37 of the specification). Applicant does not teach one of skill in the art how to make and use the claimed expression cassette, wherein introduction of the expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence as broadly claimed. The art teaches that one of skill in the art cannot predict the specific function of a transcription factor encoding polynucleotide merely on the basis of it's structural features, and that similar transcription factors can control different functions (see Riechmann *et al* 2000, Science 290:2105-2110, especially page 2109). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen though a myriad of 200 base pair fragments being 65% identical to any 200 base pair fragment of SEQ ID NO: 2, a myriad of antisense polynucleotides of said fragments, a myriad of 200 or 500 base pair fragments of SEQ ID NO: 1 and construct a myriad of expression cassettes to identify those expression cassettes wherein introduction of the

expression cassette into a plant to suppress IND1 expression results in a plant with delayed fruit dehiscence as broadly claimed.

Claim Rejections - 35 USC § 103

12. Claims 5-7 and 9-18 remain rejected and claims 34-40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ryan *et al* (1998) in view of Quattrocchio *et al* (1998). This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 May 2002. Applicant's arguments filed 15 October 2002 have been fully considered but they are not persuasive.

13. Applicant argues that Quattrocchio provides no reason to believe that all bHLH sequences would produce the same phenotypes as describe in the reference. Applicant also argues that there is no reason for one of skill in the art to ascribe any function to the Ryan sequence and therefore no reason described in the cited art for constructing an expression cassette comprising the sequence (page 11 of the Remarks). This argument is not found to be persuasive because at the time of Applicant's invention, one of ordinary skill in the art would have recognized the Ryan sequence as encoding a plant Ra transcription factor, as taught by Ryan. One of ordinary skill in the art at the time of Applicant's invention would have been motivated to make an expression cassette comprising a promoter operably linked to the sequence taught by Ryan, because one of ordinary skill in the art would know that plant transcription factors regulate expression of plant genes and phenotypes. Quattrocchio teaches how to make and use expression cassettes comprising bHLH transcription factors to modify a phenotype in a transformed plant comprising said expression

cassettes. The argument that Quattrocchio provides no reason to believe that all bHLH sequences would produce the same phenotypes as describe in the reference is irrelevant to the rejection. The sequence taught by Ryan encodes Applicant's SEQ ID NO: 2, and thus would inherently suppress IND1 expression resulting in delayed fruit dehiscence, particularly in *Arabidopsis thaliana*. In addition, one of ordinary skill in the art would know to use an antisense construct to suppress the expression of the homologous polypeptide in a homologous plant using an expression cassette comprising an antisense construct of the sequence taught by Ryan. In response to applicant's argument that Quattrocchio provides no reason to believe that all bHLH sequences would produce the same phenotypes as describe in the reference, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
27 December 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638